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The two-part bicarbonate solution of Claim ¹³27 further comprising an osmotic agent selected from the group consisting of: glucose; glucose polymers; modified starch; amino acids; peptides; and glycerol.

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Cont
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30.

The two-part bicarbonate solution of Claim ¹³27 wherein the first and second containers are constructed of a gas permeable material.

REMARKS

This Amendment is submitted in response to the Office Action mailed on August 4, 2000. The Office Action rejects Claims 1-6. In this regard, Claims 1, 2, and 5 are rejected under 35 U.S.C. § 102 and Claims 1-6 under 35 U.S.C. § 103. Applicants respectfully submit for the reasons set forth below that the rejections are improper as a matter of law and fact.

Pursuant to this Amendment, newly submitted Claims 21-30 are being added and Claims 7-20 canceled without prejudice or disclaimer. Claims 7-20 are being canceled in view of the Restriction Requirement. Applicants reserve the right to file a divisional application directed to these claims. This Amendment does not add new matter.

Claims 1, 2, and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0935967 or, in the alternative, obvious in view of this reference. Applicants respectfully submit that this rejection is not proper.

Independent Claim 1, the only independent claim that has been rejected, and the claims that depend therefrom, each include the limitation that a two-part bicarbonate solution is provided, the first part including an alkaline bicarbonate concentrate having a pH ranging from about 8.6 to 10.

The Patent Office admits that EP 0935967 discloses a pH of 8.0-8.5 on the bicarbonate side. Accordingly, as a matter of law, this reference does not anticipate any of Claims 1, 2, and 5. Of course, it is axiomatic "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). As the Patent Office itself notes, each and every claimed element of Claims 1, 2, and 5 is not identically disclosed by EP 0935967. Thus, as a matter of law and fact, this reference does not anticipate any of Claims 1, 2, and 5. Therefore, Applicants respectfully request that the rejection be withdrawn.

With respect to the obviousness rejection, Applicants respectfully submit that this rejection is not proper. As noted in Applicants' patent application, Applicants claimed invention is based on a surprising discovery that by adjusting the pH level of the bicarbonate portion of a dialysis solution, a product can be produced that avoids the need for carbon dioxide addition to the bicarbonate solution as well as the use of an expensive gas barrier material. To this end, the pH of the bicarbonate concentrate is adjusted to at least 8.6 to 10.

This is counterintuitive to what one would expect. Initially, when prepared bicarbonate concentrate has a pH of 8.0-8.4. Since it is desirable that the peritoneal dialysis solution, when mixed, has a pH of 6.5-7.6, which approximates the pH of blood, one skilled in the art would not want to increase the pH of the bicarbonate concentrate. Further, there is a concern that at higher pHs interactions can occur. Nevertheless, the inventors found that by adjusting the pH of the alkaline component upwardly with these alkaline pH values, a stable product that does not require a gas barrier is produced.

EP 0935967 does not teach such a product. Indeed, in EP 0935967, the bicarbonate is maintained at approximately its natural pH, 8.0-8.4. There is no suggestion in EP 0935967 to increase the pH of the bicarbonate above that of its natural state. Thus, Applicants respectfully submit that the obviousness rejection is not proper.

Of course, the fact that EP 0935967 can be modified to achieve Applicants' claimed invention is not dispositive of obviousness. "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability." *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). The sole suggestion set forth by the Patent Office for the obviousness rejection is that "because the prior art discloses products and uses that contain the same exact ingredients/components as the claimed invention" this renders the invention obvious. This is not the correct test for obviousness.

The question is where is the motivation to increase the pH on the bicarbonate side? Just because EP 0935967 and the claims each use bicarbonate, does not mean that it is obvious to use the same pH. Indeed, as noted above, Applicants' claimed invention of increasing the pH of the bicarbonate above its natural pH is contrary to what one skilled in the art attempting to provide a product having a physiological pH would do. Thus, where is the motivation to modify EP 0935967 to increase the pH; none has been set forth by the Patent Office. Therefore, Applicants respectfully request that the rejection be withdrawn.

Claims 1-6 stand rejected under 35 U.S.C. § 103 as being unpatentable over EP 0935967 in view of *Alexander*. *Alexander* does not remedy the deficiencies set forth above with respect to EP 0935967. In fact, *Alexander* teaches away from the claimed invention. *Alexander* teaches a one-part solution. Moreover, preferably "the pH of the solution [is] slightly on the acid side (5.4 to 6.8) . . . "

(column 4, lines 24-25). Therefore Applicants respectfully submit that the combination of EP 0935967 and *Alexander* does not render obvious Claims 1-6 and accordingly Applicants respectfully request that the rejection be withdrawn.

Claims 1-5 stand rejected under 35 U.S.C. § 103 as being unpatentable over *duMoulin* in view of *Alexander*. The *duMoulin* reference discloses a two-part peritoneal dialysis solution. The pH value of the first solution is 4.5-5.8, preferably 4.8-5.6 and especially 5.0-5.5. The pH of the second solution, although it is broadly stated to be 7.2-10.0, is preferably 7.3-8.0, and especially 7.4-7.6. The Patent Office notes, the pHs do not fall within the scope of the claimed invention.

Applicants submit, it would not be obvious to modify *duMoulin* in view of *Alexander* and achieve the claimed invention. Once again, if anything, *Alexander* teaches away from the claimed invention. In this regard, *Alexander* discloses a one-part solution. In contrast, the claimed invention relates to a two-part solution. Moreover, the pH of the *Alexander* solution is not close to that of any of the parts of Applicants' claimed solution.

There is no motivation in the art to reduce the pH of the first solution of *duMoulin* to the claimed range of 1-3. There is no motivation to select a pH range of 8.5-10.0 in *duMoulin* for the bicarbonate side. Indeed, *duMoulin* teaches away from such a motivation. *duMoulin* is concerned with pH problems and accordingly the desire of the invention is to achieve a composition having a pH values that are close to physiological pHs. See column 1, lines 37-63. Therefore, in *duMoulin*, a low alkaline pH as well as higher acidic pH value is desired. In contrast, the claimed invention relates to two solutions that are highly acidic or alkalined. Thus, Applicants respectfully submit that there is no motivation to modify *duMoulin* to achieve Applicants' claimed invention. Therefore, Applicants respectfully request that the rejection of 35 U.S.C. § 103 be withdrawn.

Claims 1-6 also stand rejected under 35 U.S.C. § 103 as being unpatentable over *Veltman* in view of *Alexander, Ing, Balteau, and Segers*. Applicants respectfully submit that this rejection is not proper. Although the *Veltman* reference, which is the principal reference relied upon by this rejection, discloses a two-part solution, there does not appear to be any disclosure in *Veltman* as to the pHs of the two sides of the solution. Rather, *Veltman* is merely concerned with obtaining a final product having a pH of 7.2 to 7.4. Indeed, it appears that the pH of the bicarbonate side is unadjusted and therefore is 8.4 or less. Accordingly, *Veltman* does not appear to disclose or suggest Applicants' claimed invention.

The remaining references do not remedy the deficiencies of *Veltman*. Once again, the prior art fails to disclose or suggest Applicants' claimed concept of an acidic first solution having a pH of 3 or less and a second solution having a pH that is at least 8.6, which is greater than the natural pH of bicarbonate. Accordingly, Applicants respectfully submit that the claimed invention is not obvious in view of the cited references.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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